

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (withdrawn) In a method for manufacturing TBO product comprising sequentially the steps of:
 - (a) oxidizing the starting material N,N-dimethyl-p-phenylenediamine, in a first reaction mixture;
 - (b) introducing a source of sulfur-containing nucleophile into said first reaction mixture, to form a first intermediate, substituted S-phenyl thiosulfate;
 - (c) further oxidizing and condensing said first intermediate with o-toluidine, to form a second intermediate, substituted S-indamanyl thiosulfate;
 - (d) further oxidizing said second intermediate, to form a TBO-containing reaction product in a third reaction mixture;
 - (e) introducing a TBO-complexing agent into at least one of said reaction mixtures; and
 - (f) separating the TBO-containing reaction product from said third reaction mixture;the improvement comprising sequentially:

(a) oxidizing a starting material, comprised of at least one compound selected from the group consisting of N,N-dimethyl-p-phenylenediamine and N-dimethyl-p-phenylenediamine, in the presence of o-toluidine in a first reaction mixture to form a first intermediate, an indamine, without forming S-phenyl thiosulfate; and then

(b) introducing a source of sulfur-containing nucleophile into said first reaction mixture form a second intermediate, S-indamanyl thiosulfate.

2. (cancelled).

3. (withdrawn) A process for manufacturing the composition of Claim 2 including the steps of :

(a) synthesizing an indamine; and
(b) synthesizing an S-indamanyl thiosulfate;

4. (withdrawn) The process of Claim 4 wherein said step of synthesizing an indamine further comprises the step of oxidizing a solution of o-toluidine and a solution of N,N-dimethyl-phenylenediamine in the presence of an acid and oxidizing agent.

5. (withdrawn) A method for identification of dysplastic tissue comprising:

the step of applying to human tissue the TBO product of
Claim 2.

6. (withdrawn) A method for treating dysplastic
tissue comprising:

the step of applying to human tissue the TBO product of
Claim 2.

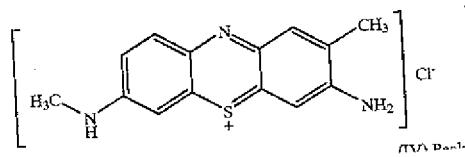
7. (withdrawn) The method for treating dysplastic
tissue of Claim 6 further comprising:

modifying the incidence of light to control phototoxic
effects.

8. (withdrawn) The method for treating dysplastic
tissue of Claim 6 further comprising:

the step of mixing a chemotherapeutic agent with said TBO
product of Claim 4.

9. (previously presented) A composition comprising:
an N-demethylated derivative of toluidine blue O having a
ring methyl group at the C-2 position, and having the
structure



wherein the *N*-demethylated derivative of toluidine blue O comprises at least 73% by weight of the total organic dye content of said composition.

10. (withdrawn) A process for manufacturing the composition of Claim 9 including the steps of :

- (a) synthesizing an indamine; and
- (b) synthesizing an *S*-indaminy1 thiosulfate;

11. (withdrawn) The process of Claim 11 wherein said step of synthesizing an indamine further comprises the step of oxidizing a solution of *o*-toluidine and a solution of *N*-dimethyl-pphenylenediamine in the presence of an acid and oxidizing agent.

12. (withdrawn) A method for identification of dysplastic tissue comprising:

the step of applying to human tissue the TBO product of
Claim 9.

13. (withdrawn) A method for treating dysplastic
tissue comprising:

the step of applying to human tissue the TBO product of
Claim 9.

14. (withdrawn) The method for treating dysplastic
tissue of Claim 13 further comprising:

modifying the incidence of light to control phototoxic
effects.

15. (withdrawn) The method for treating dysplastic
tissue of Claim 13 further comprising:

the step of mixing a chemotherapeutic agent with said TBO
product of Claim 9.

16. (cancelled).

17. (withdrawn) A process for manufacturing the composition of Claim 16 including the steps of :

- (a) synthesizing an indamine; and
- (b) synthesizing an S-indaminy1 thiosulfate;

18. (withdrawn) The process of Claim 17 wherein said step of synthesizing an indamine further comprises the step of oxidizing a solution of o-toluidine and a solution of N,N-dimethyl-p-phenylenediamine and N-dimethyl-p-phenylenediamine in the presence of an acid and oxidizing agent.

19. (withdrawn) A method for identification of dysplastic tissue comprising:

the step of applying to human tissue the TBO product of Claim 16.

20. (withdrawn) A method for treating dysplastic tissue comprising:

the step of applying to human tissue the TBO product of Claim 16.

21. (withdrawn) The method for treating dysplastic tissue of Claim 20 further comprising: modifying the incidence of light to control phototoxic effects.

22. (withdrawn) The method for treating dysplastic tissue of Claim 20 further comprising: the step of mixing a chemotherapeutic agent with said TBO product of Claim 16.

23. (withdrawn) In an HPLC method for analysis of a TBO dye product, said method including:

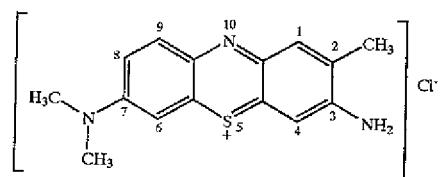
- (a) forming a TBO sample solution,
- (b) forming a mobile phase comprising a water-soluble salt of an organic acid,
- (c) equilibrating an HPLC column with the mobile phase flow, and
- (d) injecting the sample solution into the HPLC column,

the improvement for identifying sample dye components and for assaying and determining the purity of said sample, said improvement comprising:

forming said mobile phase as a composition including heptanesulfonic acid; and

forming a second mobile phase composition comprising 50% alcohol by volume.

24. (new) A composition comprising toluidine blue O having a ring methyl group at the C-2 position, and having the structure



wherein the toluidine blue O is at least about 73% by weight of the total organic dye content of the composition and wherein the composition is formed by:

(a) combining *N,N*-dimethyl-*p*-phenylenediamine, *N*-methyl-*p*-phenylenediamine, mixtures thereof, or derivatives thereof, with *o*-toluidine or a derivative thereof, to form a first intermediate, the first intermediate being an indamine or a derivative thereof;

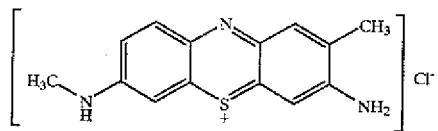
(b) combining the first intermediate with a source of thiosulfate ions, to form a second intermediate, the second intermediate being a *S*-indaminyl sulfate or a derivative thereof;

(c) combining an oxidizing agent with the second intermediate, to form a third intermediate, the third intermediate being an oxidized *S*-indaminyl sulfate or a derivative thereof;

(d) combining a complexing agent with the third intermediate, to form a toluidine blue O product mixture; and

(e) separating the toluidine blue O composition from the toluidine blue O product mixture.

25. (new) A composition comprising an N-demethylated derivative of toluidine blue O having a ring methyl group at the C-2 position, and having the structure



wherein the *N*-demethylated derivative of toluidine blue O comprises at least about 73% by weight of the total organic dye content of the composition; wherein the composition is formed by

(a) combining *N,N*-dimethyl-*p*-phenylenediamine, *N*-methyl-*p*-phenylenediamine, mixtures thereof, or derivatives thereof, with *o*-toluidine or a derivative thereof, to form a first intermediate, the first intermediate being an indamine or a derivative thereof;

(b) combining the first intermediate with a source of thiosulfate ions, to form a second intermediate, the second intermediate being a *S*-indaminyl sulfate or a derivative thereof;

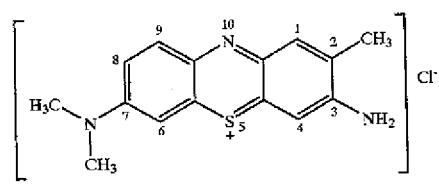
(c) combining an oxidizing agent with the second intermediate, to form a third intermediate, the third intermediate being an oxidized *S*-indaminyl sulfate or a derivative thereof;

(d) combining a complexing agent with the third intermediate, to form a toluidine blue O product mixture; and

(e) separating the toluidine blue O composition from the toluidine blue O product mixture.

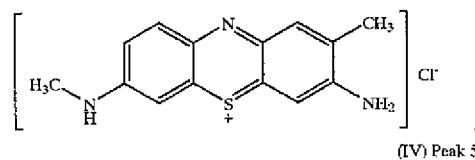
26. (new) A composition comprising:

(a) toluidine blue O, having a ring methyl group at the C-2 position and having the structure



and

(b) an N-demethylated derivative of toluidine blue O having a ring methyl group at the C-2 position and having the structure



in which (a) and (b) comprises at least about 70% by weight of the total organic dye content of the composition and wherein the composition is formed by

(a) combining *N,N*-dimethyl-*p*-phenylenediamine, *N*-methyl-*p*-phenylenediamine, mixtures thereof, or derivatives thereof, with *o*-toluidine or a derivative thereof, to form a first intermediate, the first intermediate being an indamine or a derivative thereof;

(b) combining the first intermediate with a source of thiosulfate ions, to form a second intermediate, the second intermediate being a *S*-indaminy1 sulfate or a derivative thereof;

(c) combining an oxidizing agent with the second intermediate, to form a third intermediate, the third intermediate being an oxidized *S*-indaminy1 sulfate or a derivative thereof;

(d) combining a complexing agent with the third intermediate, to form a toluidine blue O product mixture; and

(e) separating the toluidine blue O composition from the toluidine blue O product mixture.